

12 KAR 2:031. Directions for use and precautionary statements.

RELATES TO: KRS 250.501, 250.531, 250.551(1), (2), 21 C.F.R. 225.80, 225.180

STATUTORY AUTHORITY: KRS 250.521(2)(e), (f), 250.571(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 250.490 to 250.631. This administrative regulation requires that directions for feeding and precautionary statements be provided with feed containing additives to ensure safe and effective use of the product.

Section 1. Directions for use and precautionary statements on the labeling of a commercial feed and customer-formula feed containing additives, such as a drug, a special purpose additive, or nonnutritive additive shall:

- (1) Be adequate to enable safe and effective use for the intended purposes by users with no special knowledge of the purpose and use of the articles; and
- (2) Include, at a minimum, all information prescribed by:
 - (a) Applicable federal regulations under the Federal Food, Drug, and Cosmetic Act, which is codified as 21 U.S.C. 301 to 397; and
 - (b) 12 KAR 2:036, for feed containing non-protein nitrogen.

Section 2. Adequate directions and precautionary statements necessary for safe and effective use shall be placed on commercial feeds distributed to supply particular dietary needs or for supplementing or fortifying the usual diet or ration with a vitamin, mineral, or other dietary nutrient or compound.

Section 3. Raw milk distributed as commercial feed shall bear the following statement: "WARNING: NOT FOR HUMAN CONSUMPTION - THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA." This statement shall be displayed in a conspicuous manner and shall not be smaller than the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

Panel Size	Minimum Warning Statement Type Size
≤5 in. ²	1/16 in.
>5-≤25 in. ²	1/8 in.
>25-≤100 in. ²	3/16 in.
>100-≤400 in. ²	1/4 in.
>400 in. ²	1/2 in.

(AES-2 (1973)-6; 1 Ky.R. 1000; eff. 6-11-1975; 25 Ky.R. 892; 2355; eff. 4-14-1999; 45 Ky.R. 392; eff. 10-10-2018.)